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108TH CONGRESS
2D SESSION

H. R. 4377

To provide for the review by the Commissioner of Food and Drugs of the process by which the Food and Drug Administration made the decision not to approve the commercial distribution of the emergency-contraceptive drug Plan B as an over-the-counter drug, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 17, 2004

Mrs. MALONEY (for herself, Mr. GRIJALVA, Mr. CONYERS, Mr. JACKSON of Illinois, Mrs. CAPPS, Ms. MILLENDER-MCDONALD, Mr. LANTOS, Mr. CROWLEY, Ms. JACKSON-LEE of Texas, Ms. WOOLSEY, Mr. NADLER, Mr. FILNER, Ms. SCHAKOWSKY, Mr. FRANK of Massachusetts, Ms. LEE, Ms. DELAURO, and Mr. SHAYS) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To provide for the review by the Commissioner of Food and Drugs of the process by which the Food and Drug Administration made the decision not to approve the commercial distribution of the emergency-contraceptive drug Plan B as an over-the-counter drug, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Science Over Politics Act''.

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) Emergency contraceptive pills (''ECPs'') are approved for use by the Food and Drug Administration (''FDA'').

(2) Emergency contraceptive pills are a concentrated dosage of ordinary birth control pills that can dramatically reduce a woman's chance of becoming pregnant.

(3) If ECPs are taken within 72 hours of contraceptive failure or unprotected sex, ECPs can reduce a woman's risk of pregnancy by up to 89 percent.

(4) Emergency contraceptive pills do not cause abortion but rather prevent pregnancy by inhibiting ovulation, fertilization, or implantation before a pregnancy occurs.

(5) Emergency contraception cannot interrupt or disrupt an established pregnancy.

(6) Increased use of ECPs could reduce the number of unintended pregnancies and abortions by half.

(7) A 2002 study revealed that ECP use was likely responsible for up to 43 percent of the decline in abortions between 1994 and 2000, with ECP use preventing over 50,000 abortions in 2000 alone.

(8) Over-the-counter sales of ECPs would be particularly beneficial for sexual assault victims as approximately 25,000 women per year in the United States become pregnant as a result of rape. An estimated 22,000 of these pregnancies, 88 percent, could be prevented if sexual assault victims had timely access to emergency contraception.

(9) More than 70 organizations, including the American Nurses Association, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the American Medical Association, the American Public Health Association, and the Association of Reproductive Health Professionals, support over-the-counter access to ECPs.

(10) On April 21, 2003, product manufacturers Women's Capital Corporation submitted an application to the Food and Drug Administration requesting to switch the emergency contraceptive Plan B from prescription-only to over-the-counter (''OTC'') status.

(11) ECPs meet all the customary FDA criteria for over-the-counter status in that they are safe and effective, are not associated with any serious or harmful side-effects, are easily self-administered, and require no need for medical supervision. Moreover, ECPs are not harmful to an existing pregnancy and their use does not lead to riskier behavior or less frequent use of other forms of contraception, has no potential for overdose or addiction, is not harmful to an existing pregnancy, is easily self-administered, and requires no need for medical screening.

(12) FDA staff and experts appointed to the advisory committees considered volumes of evidence showing that making Plan B available over-the-counter was safe and effective for women of all reproductive age.

(13) On December 16, 2003, a joint panel of the FDA's Reproductive Health Drugs Advisory Committee and Non-Prescription Drugs Advisory Committee voted 28–0 that Plan B could be safely sold as an over-the-counter medication.

(14) On December 16, 2003, a joint panel of the FDA's Reproductive Health Drugs Advisory Committee and Non-prescription Drugs Advisory

Committee voted 23–4 to recommend that the FDA approve the application to make Plan B available over-the-counter for women of all ages.

(15) The FDA's rejection of over-the-counter status for Plan B on May 6, 2004, directly contradicted the overwhelming weight of scientific evidence.

(16) The limited options offered by the FDA for future consideration of over-the-counter sale of Plan B are not warranted by the volumes of existing evidence and run counter to the advice of the FDA's independent experts, staff, and precedent.

(17) Evidence suggests that the FDA's decision resulted from an unprecedented political takeover of what is supposed to be an independent scientific review.

SEC. 3. FDA DENIAL OF OTC STATUS FOR EMERGENCY-CONTRACEPTIVE DRUG PLAN B; REVIEW BY COMMISSIONER OF FOOD AND DRUGS.

(a) IN GENERAL.—Not later than 30 days after the date of the enactment of this Act, the Commissioner of Food and Drugs shall—

(1) review the decision of the Food and Drug Administration not to approve the supplemental application submitted under section 505(b) of the Fed-

eral Food, Drug, and Cosmetic Act to obtain approval for the commercial distribution of the drug Plan B (levonorgestrel in 0.75 mg. tablet form) as a drug that is not subject to the requirements of section 503(b)(1) of such Act (commonly known as an over-the-counter, or OTC, drug); and

(2) affirm, under penalty of law, that such decision—

(A) was not politically influenced;

(B) was based on sound science; and

(C) conformed to precedents and procedures of the Food and Drug Administration.

(b) PUBLICATION IN FEDERAL REGISTER.—The affirmation under subsection (a) shall be made through a statement published in the Federal Register.

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